

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SEVENTH

900147

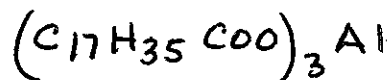
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Format
I

"INERT INGREDIENTS OF PESTICIDE FORMULATIONS"
(FORMAT FOR IDENTIFICATION AND TOXICOLOGICAL APPRAISAL)

A. EPA Accession Number and Name:

000762 Stearic acid, aluminum salt of

B. American Chemical Society Chemical Abstracts Service (CAS) Name and Registry NumberOctadecanoic acid, aluminum salt
637-12-7C. Other Names(EPA S): Aluminum stearate
(S): Aluminum tristearate
(T): Alugel 34TN; Metasap XX; Rofob 3D. Chemical Composition[CH₃(CH₂)₁₆-COO]₃ Al
(MW) 877.35E. EPA Chemical CodeF. Molecular StructureG. Chemical and Physical Properties

1. solubility - practically insoluble in water; soluble in alcohol, benzene, turpentine, mineral oils (2)
2. specific gravity (or density)
3. state, color, odor, etc.
4. MP, BP, VP
5. corrosiveness
6. technical products & impurities
7. stability

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H. Use as an Inert - defoamer (1)

I. Other Uses Active? Yes () No (X)
waterproofing fabrics, ropes; in paint and varnish driers; in cements;
photographic compositions (2)

J. Government Regulations

1. FDA - Formerly listed as an allowable coloring agent in cosmetics;
dropped from the list because there are no pending petitions for its
use. (3) May be safely used in foods as a defoaming agent subject
to 21 CFR 121.1099. (6) May be safely used in foods subject to
21 CFR 121.1071.(7)
2. EPA - 40 CFR 180.1001 - Exempted from the requirement of a tolerance
when used in accordance with good agricultural practice as an inert
ingredient in pesticide formulations applied to growing crops only. (1)
3. OSHA
4. NIOSH
5. DOT
6. Other Federal
7. State, County
8. Foreign Countries

K. Manufacturer(s) - Cary Co.; Ferro Corp.; C.P. Hall; Mallinckrodt; and
numerous other manufacturers and suppliers (5)

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L. Environment

1. Effect
2. Conversion Products (Metabolites, Degradation Products)
3. Fate
4. Persistence
5. Bioaccumulation

M. Toxicology

1. Human effects
 - a. Occupational Studies
 - b. Epidemiology
 - c. Metabolic Effects Studies
 - d. Poisoning Incidents and Case Studies
 - e. Others

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2. Non-Human Mammalian Effects

- a. Acute toxicity
- b. Pharmacology
- c. Absorption/Excretion
- d. Metabolism
- e. Subacute
- f. Sensitization
- g. Teratology - A test for teratogenicity in rabbits using a vaccine adjuvant proved negative. The compound, which contained 2% Aluminum stearate, was injected into rabbits on the eighth day of pregnancy and had no apparent effects on fetal development. (4)
- h. Mutagenicity
- i. Carcinogenicity
- j. Other Chronic Effects (Both Reversible and Irreversible) - Long term observations were carried out in guinea pigs and monkeys given multiple injections of a vaccine adjuvant containing 2% aluminum stearate. There was no evidence of immunopathologic lesions, tumor formation, or other pathological processes. (4)
- k. Behavioral Effects
- l. Synergism
- m. Other

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N. Recommendation: Class 4

This compound when used as an inert ingredient in pesticide formulations, poses no hazard to animal or human health. (See recommendations on stearic acid and sodium aluminate). Aluminum stearate provides a less available form of aluminum for alimentary absorption.

O. Sources used in Search

1. On Line Data Bases

- a. Toxline
- b. Medline
- c. Chemline
- d. Other

2. Major References

- a. The Merck Index
- b. NIOSH Registry of Toxic Substances
- c. Chemical Abstracts
- d. Biological Abstracts
- e. Other

P. References and Review Articles

- () U.S. Environmental Protection Agency, Office of Pesticide Programs, Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels, U.S. G.P.O., Washington, D.C.: 1975.
- () Chemical Rubber Publishing Co., Handbook of Chemistry and Physics, 57th Ed., Cleveland, Ohio: 1976-1977.
- () Condensed Chemical Dictionary, 8th Ed., Van Nostrand-Rheinhold Co., New York: 1971.
- (2) Merck and Co., The Merck Index, 9th Ed., Rahway, N.J.: 1976.
- () National Institute of Occupational Safety and Health, Registry of Toxic Effects of Chemical Substances, U.S. G.P.O., Washington, D.C.: 1976.
- () Association of American Pesticide Control Officials, Inc., Pesticide Chemical Official Compendium, Topeka, Ks.
- () Farm Chemicals Handbook, Meister Publishing Co., Willoughby, Ohio: 1975.
- () McCutcheons Detergents and Emulsifiers, Allured Publishing Co., Ridgewood, N.J.: 1973.
- () U.S. Food and Drug Administration, Department of Health, Education & Welfare, GRAS Monograph Series.
- () World Health Organization, IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, Geneva.

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P. References and Review Articles (cont.)

- (1) U.S. E.P.A., Code of Federal Regulations; 40, part 180.1001, Washington, D.C.: 1976.
- (3) Anonymous, Termination of provisional listing for color additives, Federal Register; 41, Issue 186, pp 1855-6, 1976.
- (4) Peck, H.M., A.F. Woodhour, and M.R. Hilleman, New metabolizable immunologic adjuvant for human use - Chronic toxicity and teratogenicity tests, Proc. Soc. Exp. Biol. Med.; 128, Issue 3, pp 699-708, 1968.
- (5) Oil, Paint and Drug Reporter, OPD Chemical Buyers Directory, Schnell Publishing Co., New York: 1974.
- (6) U.S. F.D.A., Code of Federal Regulations; 21, part 121.1099, Washington, D.C.: 1976.
- (7) Ibid., part 121.1071.

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(FORMAT FOR IDENTIFICATION AND TOXICOLOGICAL APPRAISAL)

Format
II

A. EPA Accession Number and Name:

000762 Stearic acid, aluminum salt of

B. Description

C. Use as an Inert

D. Problems Encountered

000762 Stearic acid, aluminum salt of
000295 Stearic acid, aluminum salt of
same name, two numbers, 295 deleted, refer to 762
000296S Aluminum stearate
000762S Aluminum stearate
same name, two number, 296S deleted, refer to 762S

E. Recommendation

F. Sources Used in Search

1. On Line Data Bases

- a. Toxline
- b. Medline
- c. Chemline

2. Major References

- a. The Merck Index
- b. NIOSH Registry of Toxic Substances
- c. Chemical Abstracts
- d. Biological Abstracts



13544

R101169

Chemical: Aluminum - magnesium stearate

PC Code: 900147

HED File Code 13100 Other Tox Documents

Memo Date: 01/01/87

File ID: 00000000

Accession Number: 412-05-0037

HED Records Reference Center
10/15/2004